III. ADMINISTERING THE QUESTIONNAIRES

A. Overview of the Study Questionnaires

1. Telephone Interviewing Administration Schedule

The CNMC telephone interviewing staff will conduct a total of five telephone interviewers with each study participant. These interviews will be administered at baseline (i.e., within one month of enrollment prior to the infant's delivery), at 6-weeks postpartum, and at 4-, 6-, and 12-months postpartum.

The "Opening Date" for all baseline telephone interviews is the same date the mother is enrolled into the study. It is critical that the baseline interview be completed as soon as possible while the mother is still pregnant. Any participant who does not complete the baseline telephone interview prior to delivery will be terminated from the study. For follow-up interviews, the "Opening Date" is 2-weeks prior to actual assessment period (e.g., for the 6-week interview, the opening date would be when the baby reaches 4-weeks of age). Closing dates for each telephone interview assessment are listed below. If the mother has not completed the interview by the closing date, then she is assigned a final result code indicating that interview will not be completed (see *Section C.5* for further information regarding final result codes) and the data will be considered "missing." The decision to terminate a mother's participation based on repeated missing data events will be handled on a case-by-case basis in collaboration with the Study PI.

Event:	Closing Date:
Baseline Telephone Interview:	Delivery of baby
6-Week Telephone Interview:	3-months postpartum
4-Month Telephone Interview:	5-months postpartum
6-Month Telephone Interview:	9-months postpartum
12-Month Telephone Interview:	15-months postpartum

2. Questionnaire Content

The telephone interviews are designed to collect the following types of information: demographic background; pregnancy and family medical history, maternal and partner feelings about current pregnancy; tobacco use and exposure to other people's cigarette smoke during pregnancy; strategies to reduce tobacco use and exposure; sources of support to quite smoking and/or reduce smoke exposure; drug and alcohol use during pregnancy; maternal mental health status and feelings of self-efficacy and control; partner abuse; and sources of social support (including partner and family/friends). Postpartum telephone interviews will also include questions regarding infant health, growth and development; utilization of infant health care services; infant care practices (e.g., breastfeeding practices) and temperament; parent-infant relationship, attitudes, and behaviors; tobacco use and maternal and infant exposure to other people's cigarette smoke after pregnancy; and supervisory and safety knowledge and practices.

B. Getting Started

1. Contacting and Scheduling Participants for Telephone Interviews

On a daily basis, you will need to generate the *CNMC Telephone Interview Report* from the Data Management System. This report includes a list of all participants who are in need of a telephone interview. The report indicates (1) the type of interview needed (e.g., baseline, 6-week, etc.); (2) whether or not the home visit has already been scheduled, and if so, the date and time of the appointment; and (3) contact information for the participant so that you may confirm appointment times and/or schedule an appointment as needed. For an example of the *Telephone Interview Report* and steps for generating this report, refer to the *DMS Manual of Operations*.

Once you have generated this report, you may use this report to confirm or scheduled appointments with participants. Generally, all baseline telephone interviews will be scheduled ahead of time by the Clinic RA when the mother is enrolled into the study. If for some reason, none of the telephone interviewing staff can conduct an interview at the date and/or time scheduled, a designated interviewer will need to call the mother to re-schedule the interview. When calling to re-schedule, you may also attempt to complete the interview at that time (if both you and the mother have the time).

All participants with a scheduled appointment MUST be called the day before their appointment to confirm the appointment time. If the appointment falls on a Monday, the participant MUST be called the Friday before the appointment. If a participant's name appears on this report and an interview has not been scheduled, begin calling the participant as soon as possible to schedule his/her appointment. This is especially critical for the baseline telephone interview, since this interview must be completed before the mother delivers her baby. When calling to schedule or confirm the telephone interview, you may explain that the telephone interview should only take 1-2 hours.

2. Initiating a File Folder

For all new interviewing cases that appear on the report (i.e., all new baseline cases), you will first need to initiate a file folder for the participating woman. First you will generate from the DMS a page of labels of her Subject ID Number. (This procedure is explained in the *DMS Manual of Operations*.) These labels will be affixed to all forms that are generated for the woman, including the study questionnaires and *Telephone Interviewing Activity Booklet*. A label should also be affixed to the outside of the file folder. To prepare you for contacting the woman to administer the baseline interview, affix a label on a blank baseline questionnaire and place it in the folder. Finally, you will initiate a *Telephone Interviewing Activity Booklet* (see *Section B.3* below) which is used to document activities related to the administration of the evaluation questionnaires.

3. Initiating the Telephone Interviewing Activity Booklet

Prior to calling the mother to confirm or schedule the baseline telephone, you will need to initiate a *Telephone Interviewing Activity Booklet* by completing Section A of the booklet. A

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copy of the *Telephone Interviewing Activity Booklet* is included at the end of this chapter. Section A (mother's name, baby's name, and telephone numbers) can be completed using information from either the *Telephone Interviewing Report*, *Face Sheet*, and/or the *Individual Activity Summary Report* in the DMS. Instructions for accessing this information from the DMS are included in *DMS Manual of Operations*. Once you initiate the *Telephone Interviewing Activity Booklet*, you will use this booklet to document (1) the completion of all telephone interviews and (2) all attempted and completed contacts with the participant, including all attempts to schedule and complete telephone interview appointments (in Section C of the booklet).

C. Ending the Interview

1. Updating Contact Information

At the end of each telephone interview, you should ask the mother if there are any changes to her contact information (e.g., home address, home, work, and cellular telephone number, etc.). When updating contact information, you need to:

- verify whether the existing information is still accurate
- try to obtain information that is missing
- determine whether any new information should replace existing information

All changes should be documented in the *Telephone Interviewing Activity Booklet* which will then be entered into the DMS. Procedures for updating contact information in the DMS are provided in the *DMS Manual of Operations*.

2. Scheduling the Next Interview

In addition to updating contact information, at the end of each telephone interview, you will also need to schedule the date and time for the next telephone interview. Although, the interviews are scheduled months apart, attempt to schedule an exact date and time, if possible. If for some reason this is not possible, ask the mother when she thinks may be a good time to call to either conduct or schedule the interview (e.g., weekday evenings). Record any scheduling information on the cover page of the telephone interview and in Section B of the *Telephone Interviewing Activity Booklet*. This information will also be entered into the DMS as discussed in *Section C.4* below.

3. Compensation

Compensation for completing the telephone interviews will be provided to each participant in conjunction with the home visit assessment activities. Specifically, there are a total of five assessments for ETS. The first two assessments (baseline and 6-week postpartum assessments) each include a telephone interview and two home visits. Participants are given \$25 for completing each of these assessments. The third assessment (4-month postpartum assessment) includes a telephone interview only; participants are given \$15 for completing this assessment. The last two assessments

(6 and 12-month assessments) each include a telephone interview and two home visits; participants are given \$25 for the 6-month assessment and \$40 for the 12-month assessment. Therefore, participants can receive up to a total of \$130. A summary of the ETS study activities and compensation provided is displayed in *Chapter 1*, *Section D.5.a* of this manual.

Distribution of incentive payments will be given to the mother by either the Clinic RA or Home Visitor ONLY if the mother has already completed the telephone interview and all home visit activities. Therefore, as a CNMC telephone interview, you will not need to worry about payment the mother her incentive for completing the telephone interview. You may remind her, however, that in order to receive her incentive, she must complete both the telephone interview and home visit activities, and encourage her to complete both home visits, as appropriate. The only exception is the 4-month assessment which involves a telephone interview only.

4. Updating the Telephone Interviewing Activity Booklet

The *Telephone Interviewing Activity Booklet* is used to document all attempted and completed contacts with the participant (for the purpose of administering the telephone interview) and the actual completion of each telephone interview. Specifically, at the end of each telephone interview, you will need to document the following information in Section B of the *Telephone Interviewing Activity Booklet* for the appropriate time period (e.g., baseline, 6-weeks, etc.:

- scheduling information for the next interview (e.g., date/time of scheduled interview or best times to call the mother for the next interview);
- any updated contact information (e.g., change in telephone number);
- whether or not there are any new health care providers reported by the mother during the interview which need to be entered into the DMS; and
- the final result code for the interview, date completed, and interviewer's initials.

This information will then be entered into the DMS at the conclusion of the telephone interview. Step by step instructions for entering data from the *Telephone Interviewing Activity Booklet* into the DMS are included in the *DMS Manual of Operations*. Section C of the *Telephone Interviewing Activity Booklet* is used to document all telephone and in-person contact attempts; this information does not need to be entered into the DMS.

5. Assigning Final Result Codes

The result codes provided in Section B of the *Telephone Interviewing Activity Booklet* should be used to code the outcome for each interview. For most pending situations that you encounter, such as "no one home" or "trying to locate," you will simply describe these pending situations in Section C of the booklet (Appointment and Contact Log) and not enter anything into the DMS. Until you assign a final result code to the case, the DMS will "assume" that it is still being worked. The final result codes are:

02 <u>INTERVIEW COMPLETED</u>: Assign this code in Section B and enter it into the DMS when you have completed an evaluation interview.

- O3 <u>INTERVIEW PARTIALLY COMPLETED</u>: Assign this code in Section B and enter it into the DMS when the interview is only partially completed and you were never able to reach the woman to complete it. Explain the circumstances in the Notes section for that particular task.
- 91 <u>SUBJECT DISCONTINUED/DELIVERED BEFORE BL COMPLETED</u>: This code can only be assigned to baseline interviews. Assign this code if you are not able to complete or partially complete the telephone interview before the participant delivers her baby. If you are not able to complete the interview prior to delivery of the baby, the participant will be terminated from the study. Upon determining the baby's delivery date, be sure to update the delivery information in Add/Update Face Sheet option in the DMS (refer to *DMS Manual of Operations* for more detailed instructions).
- 92 <u>UNABLE TO LOCATE, FINAL</u>: Assign this code in Section B and enter it into the DMS when your tracing efforts have been unsuccessful (e.g., you are not able to obtain a working telephone number or other way of reaching the mother by telephone). Once this code is entered into the DMS, the participant will no longer appear on the *Telephone Interviewing Report* for that particular activity. If it is the baseline interview, the woman will be dropped entirely from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her "window of time" will reopen for the next scheduled interview, and she will not be given the compensation payment for the incomplete interview.
- 93 <u>SUBJECT UNAVAILABLE</u>: Assign this code in Section B when you have been unable to contact the woman to administer the interview within the "window" of time. Explain the circumstances in Notes section for that particular task. Typically, for this code, you will have a working telephone number; however, the participant (for whatever reason) is never available to complete the interview. Once this code is entered into the DMS, the participant will no longer appear on the *Telephone Interviewing Report* for that particular activity. If it is the baseline interview, the woman will be dropped entirely from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her "window of time" will reopen for the next scheduled interview, and she will not be given the compensation payment for the incomplete interview.
- OTHER FINAL OUTCOME: Assign this code in Section C and enter into it into the DMS for any other final outcome that results from an attempt to administer an evaluation interview. Explain the circumstances in Notes section for that particular task. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her "window of time" will reopen for the next scheduled interview, and she will not be given the compensation payment for the incomplete interview.

- 97 <u>NOT APPLICABLE</u>: It is unlikely that this code will need to be used. If, however, you find a reason to use this code, be sure document the reason in the Notes section for that particular task and to discuss the situation with the Study PI to determine whether or not the participant may continue with the study.
- 99 <u>REFUSED</u>: Assign this code in Section B and enter it into the DMS when the participating woman refuses to be interviewed. Explain the circumstances in Notes section for that particular task. If it is the baseline interview, the woman will be dropped from the study and will not be able to participate. If it one of the prenatal follow-up interviews, her "window of time" will reopen for the next scheduled interview, and she will not be given the compensation payment for the incomplete interview.

6. Editing the Questionnaire

Immediately after you complete an interview, but before you get off the telephone with a participant, scan the form for omissions or incomplete items. Then, conduct a more thorough edit immediately after getting off the phone with the respondent, so if there is any reason to contact her to clarify or complete an item, you can reach her immediately. Further information regarding editing procedures is discussed in *Chapter IV*.

7. Entering Health Care Provider Information into the DMS (Postpartum Interviews Only)

Once you have edited the questionnaire, updated the *Telephone Interviewing Activity Booklet*, and entered the information from the booklet into the DMS, you will then need to enter/update contact information for all infant health care providers reported by the mother during the interview into the DMS. For the 6-week postpartum interview, you will enter the information for all providers reported; for the remaining post-partum interviews, you will only need to enter information for new providers reported by the mother. Instructions for entering this information into the DMS are included in the *DMS Manual of Operations*.